

Homeland Security Laboratory
BSL4 Utah Recommendations
from the **State Advisory Council on Science and Technology**
October 2nd, 2002

The National Institutes of Health (NIH) has received a significantly increased budget to cover the development of technologies that sufficiently protect the American public from pathogens that have no known therapy or vaccine. This will be implemented and managed through the creation of Regional Centers of Excellence (RCE). Each RCE will have an assigned Regional Biocontainment Laboratory (RBL). The RBL must be a facility that achieves a Bio Safety Level 4 (BSL4). Utah State University (USU) is submitting a proposal to establish an RBL within Utah. This document focuses on the potential creation of that RBL or BSL4 within the state of Utah

We asked several questions and then derived recommendations from our findings. The questions are fundamental for the topic and are at a top level. Follow-on questions can be answered in the provided detail and through further research. We asked:

Primary Questions

- What is a BSL4 Laboratory and is it Safe?
- What occurs at a BSL4?
- What impact will a BSL4 have in Utah?
- Why build a BSL4 at all?
- Why build a BSL4 in Utah?
- Should we pass on the opportunity of a BSL4 in Utah?

Once we had enough information to answer these questions we derived a series of recommendations based upon the results. These are general in nature and intended to help provide guidance in developing public policy concerning the creation of a BSL4 facility in Utah. In support of a positive or negative, passive or aggressive decision, we suggest:

Recommendations

1. To realize the full potential and associated benefits of locating a BSL4 in Utah there must be intensive and broad collaborations of biotech industry professionals and all research universities.
2. The public must be effectively educated on a frequent basis about the facts of a BSL4, its relationship to homeland defense and the promise of its success.
3. An objective, fact based site selection must be made. Factors to include in that decision are access, security, public involvement, isolation and manageability.
4. As a duty in support of homeland defense, leverage to the fullest extent possible, Utah's unique collection of bio-defense assets.

Additional detail is provided for each of the questions mentioned above. It is from this detail that the supplied recommendations were made.

What is a BSL4 Laboratory?

A Bio Safety Level IV facility is the most rigorous, safe and non-proliferating biological containment facility available. The three lower level facilities (BSL1-BSL3) take decreasing precautions against the spread of the pathogens under research. The primary methods of insuring safety are the usage of very small amounts of pathogen and cascading, negative pressure containment rooms. Air flows into the room through all openings and out through a series of HEPA filters. Significant autoclave systems are used to fully decontaminate all containers, instruments, and clothing. The following points are relevant about a BSL4 facility:

1. Only viruses are studied, they are not necessarily more infectious than non-BSL4 pathogens.
2. Pathogens are identified for a BSL4 because they have no effective human or animal therapy.
3. A BSL4 stores very minute quantities of pathogens and does not create them.
4. Safety is the fundamental purpose and design basis for all BSL4s.
5. Other BSL4 facilities throughout the nation are located in populated areas.
6. Of the 6 existing BSL4 facilities, 4 are military.
7. The new NIH supported BSL4 facilities will be public facilities.
8. Among BSL2 and 3 technicians, .0005 infections per person-year are documented.

What occurs at a BSL4?

The BSL4 will be used for research on pathogens - all viruses - that currently have no known effective therapy and are dangerous to the human and animal population. Research at the proposed BSL4 facility will be limited to:

Real-time detection	Developing technologies to determine the presence of these pathogens in the environment
Diagnostics	Development of techniques to detect the presence of these pathogens in humans or animals
Therapy	Development of medications or procedures to treat animals or humans that are infected
Prevention	Development of strategies to immunize animal and human populations (e.g., vaccines)

The development of these therapies and strategies will reduce the criticality of BSL4 pathogens and as Dr. Michael Keene, Utah State Science Advisor stated “to turn BSL4 pathogens into BSL3 pathogens”

What impact will a BSL4 have in Utah?

Only small, direct economic benefit can be derived from the ongoing operations of the facility - less than \$15 million annually. Additionally, only a modest economic benefit will be seen from the one time construction of the facility - less than \$150 million. The facility (and others) will be financially supported by NIH's recently increased annual budget of \$1.7 billion.

The direct economic benefits resulting from the creation of a BSL4 facility in Utah are arguably small. The indirect benefits are large.

Research on viruses that require a BSL4 laboratory has the potential to yield insights that go far beyond the primary virus of focus. Witness the proliferation of knowledge in molecular biology, immunology and cancer research that resulted from research on HIV, the virus that causes AIDS. Utah's research and growing biotechnology sectors can benefit from BSL4 access and results.

Utah has major virology and other pathogen research at USU, U of U and BYU. Only BSL3 facilities exist in Utah today.

Why Build a BSL4?

The creation of a BSL4 facility provides a capability that is NOT readily available elsewhere. It is exactly those capabilities that the NIH is spreading throughout multiple regions within the United States. Some reasons for building this facility are:

Handle Unknowns	When a unique infection is initially diagnosed, it may be incorrectly identified or identified as an unknown. Only a BSL4 can properly identify and handle a BSL4 pathogen. If it is unknown it must be handled at the highest BSL facility available.
Greater Public Safety	Once properly integrated into Utah's first response system, an increase in public safety will be demonstrated through faster response and less disruption.
Virus Research	Research on these pathogens can only be carried out in a BSL4. Without the stable existence of these facilities, the significant time investment of therapy and vaccine development cannot take place.
Homeland Defense	The public risk of infection from BSL4 pathogens (Ebola, hemorrhagic fevers, Marburg, etc) is a growing threat. Since these pathogens have no effective therapy, intentional or unintentional wide spread infection could be catastrophic.

Why Build a BSL4 in Utah?

Once the understanding exists that a BSL4 is required to achieve therapies and preventions for these deadly pathogens, the next major question is why in Utah. We found:

World Class Expertise	Utah's unique circumstances have created a 'gem' in the bio-defense community. We have world class expertise at USU, BYU, U of U and DPG.
First Response	As a result of hosting the Olympics, Utah has a fully developed bio-defense first response infrastructure that is now used as a model throughout our nation.
Bio-Tech Industry	Utah continues to focus on nurturing its aggressive, emerging bio-tech industry. A nearby BSL4 will strengthen the catalyst.
Inhospitable Physical Environment	The prevalent dry heat and high sun exposure within the state are a very inhospitable climate for pathogens to survive naturally. These pathogens would die almost immediately outside of the lab, in any foreseeable release scenario.
Isolation Possibilities	The large, expansive isolated regions within the state serve to potentially isolate large human and animal populations from BSL4 pathogens
Established Leadership	The Bio-Defense industry already views Utah as a leader in the field. This opportunity allows us to sustain our scientific leadership.
Broad Contact	Given that many Utah citizens travel widely throughout the world, a local BSL4 facility enables us to better counter inadvertent returned pathogens.

Should we pass on the opportunity of a BSL4 in Utah?

All opportunities have options. One such option is to not support the construction of a BSL4 facility within Utah. These are some of the points that support passing at this time.

Other BSL4 Labs	Since the reason for building a lab here in the first place is that NIH is going to build them around the country, Utah could potentially use those facilities built in other regions.
Perception of Increased Risk	Since the occurrence of these pathogens are rare in nature and not naturally located in Utah, bringing these pathogens into the state increases the risk of exposure to the human and animal population of the state.
Uncertainty of Future Uses	Utah's unique history of chemical and biological warfare

development programs place general distrust on the future usage of a BSL4 facility—even one that is used to study *defensive* (not offensive) strategies.

Perception of Lack of Need Since these pathogens are not in Utah today and there are others researching the problem we don't really need to build a facility.

This document was developed at the request of the Department of Environmental Quality for presentation to the Governor of the State of Utah. Although the information provided in this document is factual to the best of our knowledge, further research and public discussion will be warranted as Utah moves forward with BSL4 facility planning.

Reference

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5. Erik Croddy with Clarisa Perez- Armendariz and John Hart; "Chemical and Biological Warfare, A Comprehensive Survey for the Concerned Citizen", 2002
6. <http://www.niaid.nih.gov>
7. Dawn House; "Dugway Seeks Wider Mission", Salt Lake Tribune, Section A1/A4, September 23, 2002
8. Facility review, conducted by the authors, with the assistance of DPG Director Jeff Mohr, September 23, 2002.
9. Rand Review, "Homeland Security", Summer 2002, Volume 26, Number 2, various articles.
10. Kenneth I. Shine, 2002, "Memorandum to the President: Setting Goals for Relevant Medical Research to Enhance Biological Security", The Rand Institute, 6 pp.

The State Advisory Council on Science and Technology (SAC) met as a full body and created a sub-committee to handle this effort. View this report and other SAC information at <http://dced.utah.gov/science/>.

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